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| EXAMINER | |
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| DIXON, ANNETTE FREDRICKA | |
| ART UNIT | PAPER NUMBER |
| 3771 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,011 | BOEHM ET AL. | |
| | Examiner | Art Unit | |
| | Annette F. Dixon | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/6/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, GB-A-408856 (Page 3, Line 19), and WO-A-98/53869 (Page 4, Line 4) are listed in the specification, but not on the information disclosure statement.

### *Specification*

2. The disclosure is objected to because of the following informalities: Applicant refers to the claims within the specification. For example: Page 2, Line 13: "...the features in claim 1". Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

`Arrangement of the Specification`

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United

States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention

described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

## *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 27, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, in claims 1, 3, 4, and 7-9, Applicant recites "one of the two alae of the user's nose", "one of the user's nostrils", and "one nostril". This clause (and other similar clauses) appears to positively recite a portion of the human body and is considered to be directed to non-statutory subject matter. 1077 OG 24 (April 21, 1987). Dependant claims 2-34 incorporate(s) the non-statutory subject matter recited in the claims from which they depend. Applicant can overcome this rejection by reciting "*adapted to/configured to*... one of the two alae of the user's nose."

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-6, 8-10, 13-16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672).

As to Claims 1, 18, 29, and 30, Chantrel discloses a therapeutic aerosol device with a nebulizer device (2) with an aerosol generator (Column 4, Line 54 thru Column 5, Line 2) to which a gaseous medium for the generation of a main aerosol flow may be supplied from a supply device, and a pressure connection device (7) to supply pressure fluctuations which are superimposed on the aerosol main flow (51), and a nosepiece (2b) for supplying the aerosol into one of the two alae of the nose of a user connected to the nebulizer device (2). (Figure 1). Yet the Chantrel does not expressly disclose the use of a flow resistance device for use in the other of the two alae of the user's nose. However, at the time the invention was made the use of a flow resistance device was known. Specifically, Djupesland teaches the use of a flow resistance device in combination with a nose piece for the purpose of improving the deposition of aerosol particles in the nose and paranasal sinuses. (Page 19, Line 20 thru Page 20, Line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chantrel to include a flow resistance device, as taught by Djupesland for the purpose of providing a positive pressure environment in order to assist in the delivery of medicament during treatment.

As to Claim 3, the system of Chantrel and Djupesland teaches a nosepiece is embodied at one end for attachment to a connecting piece in the nebulizer device and at the other end for introduction into one nostril and the tight sealing of one of a user's nostril. Specifically, Djupesland teaches a nosepiece (30) for introduction into the nostril of a user and connected to a nebulizer (via medicament supply unit, 32). (Figure 3).

As to Claims 4 and 5, the system of Chantrel and Djupesland teaches the end of the nosepiece embodied for introduction into one nostril is embodied in the form of a truncated cone. Specifically, Djupesland teaches a truncated cone. (Figure 3).

As to Claims 6, 31, and 32, the system of Chantrel and Djupesland teaches a truncated cone shaped end of the nosepiece yet does not expressly disclose the connection angle. However, at the time the invention was made the angle of the truncated cone would be selected based upon the patient characteristics (neonate, child, adult, elderly) for the purpose of ensuring optimization of medicament in patient treatment. (Page 21, Lines 10-19). Moreover, Applicant has not asserted that the specific range recited provides a particular advantage, solves a stated problem or serves a purpose different from that of optimizing medicament delivery.

As to Claims 8 and 9, the system of Chantrel and Djupesland teaches a flow resistance device embodied for introduction into the other of the user's nostrils. Specifically, Djupesland teaches a flow resistance device (36).

As to Claim 10, the system of Chantrel and Djupesland teaches the flow resistance device includes a filter device. Specifically, Djupesland teaches a filter maybe utilized as a flow resistor (Page 15, Lines 13-14).

As to Claims 13-15, the system of Chantrel and Djupesland teaches the flow resistance device with a stopper in the form of a truncated cone. Specifically, Djupesland teaches a flow resistance device (36) and a truncated cone (40) with a first diameter on the top of the cone and a second diameter on the base of the cone. (Figure 3).

As to Claims 16, 19-21 and 33, the system of Chantrel and Djupesland teaches pressure fluctuations during the administration of treatment utilizing the aerosol device. Specifically, Chantrel teaches air is pulsed via air source (pump, 4); which provides a gas source to the nose piece (2b). (Figure 1).

As to Claim 22-24, the system of Chantrel and Djupesland teaches a sensor device for determining the aerosol flow or pressure fluctuations. Specifically, Djupesland teaches a sensor (43) coupled to a control unit (44) for controlling the flow rate of aerosol for the purpose of optimizing the particle deposition efficiency within the nasal airway. (Page 21, Line 1 thru Line 19).

As to Claim 25, the system of Chantrel and Djupesland teaches the use of multiple medicaments in the use of the nebulizing device. Specifically, Djupesland teaches the use of multiple medicaments including the administration of decongestants, anti-histamines, cromoglycates, steroids, and antibiotics. (Page 2, Lines 3-10).

As to Claim 26, 27 and 34, the system of Chantrel and Djupesland teaches the particle distribution size of the delivered medicament. Specifically, Djupesland teaches the particle distribution size within the range of about 1 to 10 micrometers. (Page 6, Lines 1-2).

As to Claim 28, the system of Chantrel and Djupesland teaches a handheld device. Specifically, Djupesland teaches the medicament supply unit (32) can be incorporated into a metered dose inhaler, which is a handheld device. (Page 18, Line 18-24).

8. Claim 2, 11, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Brugger (DE3238149).

As to Claim 2, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a suction channel. However, at the time the invention was made the use of a suction channel was known. Specifically, Brugger teaches the use of a suction channel in order to control the flow of the liquid droplets administered. (Page 3, Line 10 thru Page 4, Line 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include the suction channel, as taught by Brugger to enable control of the medicament administration to the patient.

As to Claims 11 and 12, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the connection of the flow resistance device to the nosepiece. However, at the time the invention was made the use of a connection element between the two elements placed within the nose were well known, as taught by Brugger (Figure 1) to enable close placement of the device for operational use. Therefore, it would have been obvious to one having ordinary skill in

the art at the time the invention was made to modify the system of Chantrel/Djupesland to include a connection piece between the elements, as taught by Brugger, to enable the device to be compact and connected.

As to Claim 17, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a meandering airflow channel. However, Brugger teaches the channel formation enables a smooth laminar transition from the airflow unit to the medicament to be delivered to the patient. As well known in the art, medicament is best administered to a patient in laminar flow rather than turbulent flow. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to provide a means for transitioning the airflow profile of medicament delivered to the patient, as taught by Brugger for the purpose of ensuring optimal treatment.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Landis et al. (5,687,715).

As to Claim 7, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a balloon on the nose piece for the purpose of providing a seal to the patient's nose. However, at the time the invention was made the use of a balloon seal in a nasal interface was known. Specifically, Landis teaches a balloon (130) for insertion into the nares of a patient for

the purpose of providing a sealing engagement and enabling patient comfort. (Figure 6 and Column 7, Line 55 thru Column 8, Line 18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include a balloon seal, as taught by Landis for the purpose of providing patient comfort.

***Double Patenting***

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 1, 2, 11, 13, 14, 16, 19, 20, 25, 26, 27, 30, 32, 33, and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 5-7, 10-14, and 27-29 of copending Application No. 11/650,817. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1 and 3 are a merely broader than copending claim 1. The difference lies in the fact that the copending claim includes many more elements and is thus more specific. Thus the invention of copending claim

1 is in effect a "species" of the "generic" invention of instant claims 1 and 3. It has been held that the generic invention is "anticipated" by the "species" See In Re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1 and 3 are anticipated by claim 1 of the copending application, it is not patentably distinct from copending claim 1.

With respect to all the claims, the copending application the recites a therapeutic aerosol device comprising a nebulizer device, a nosepiece, a flow resistance device, and a connection device; while the instant application recites a therapeutic aerosol device comprising a nebuliser device, nosepiece, flow resistance device, and connection piece. Applicant is advised, when two claims in applications are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The limitations of claim 2 are recited in copending claim 13. The limitations of claim 13 are recited in claim 5 of the copending application. The limitations of claims 14 and 32 are recited in claim 6 of the copending application. The limitations of claim 16 are recited in claim 7 of the copending application. The limitations of claims 19 and 33 are recited in claims 2 and 11 of the copending application. The limitations of claim 20 are recited in claim 12 of the copending application. The limitations of claim 25 are recited in copending claim 27. The limitations of claims 26 and 34 are recited in copending claim 28. The limitations of claim 27 are recited in copending claim 29.The limitations of claim 30 are recited in copending claim 14.

12. Claims 1, 2, 11, 13, 14, 16, 19, 20, 25, 26, 27, 30, 32, 33, and 34 are directed to the same invention as that of claims 1, 2, 5-7, 10-14, and 27-29 of commonly assigned Application No. 11/650,817. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Papania (7,225,807) and Djupesland (6,715,485).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

1/16/08